

REMARKS

This is a full and timely response to the outstanding non-final Office Action mailed April 12, 2010. Claims 1-5 and 9-13 are pending in the present application. Through this response, claim 1 has been amended and claims 14-16 have been canceled without prejudice, waiver, or disclaimer. Reconsideration and allowance of the application and pending claims are respectfully requested.

Claim Rejections – 35 U.S.C. § 112

1. Claim 9 is rejected under 35 U.S.C. § 112, second paragraph as being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Claim 9 was rejected as being incomplete for omitting essential elements, which is the structure of the pyrophosphate compound. As Examiner correctly noted, the structure was inadvertently omitted from previous claim sets. Applicants have included the structure in claim 9 and indicated in the claim status identifier that claim 9 is in its original form. The rejection of claim 9 under 35 U.S.C. 112, second paragraph can therefore be withdrawn.

2. Claims 14-16 are rejected under 35 U.S.C. § 112, first paragraph as the specification, while enabling for inhibition of calcification in human subjects as disclosed in the specification page 22, lines 4-5, does not reasonably provide enablement for prophylactically treating vascular calcification human subjects. Applicants have canceled claims 14-16 without prejudice, waiver, or disclaimer, and therefore rejection of these claims can be withdrawn.

In addition, Applicants note that the “Nature of the Invention” on page 5 of the Office Action is incorrect. Moreover, Applicants do not admit, acquiesce to, or waive its right to dispute the recited “relative level of skill possessed by one of ordinary skill in the art” recited on page 5 of the Office Action.

Claim Rejections – 35 U.S.C. § 102

3. Claims 1, 5, 11-14, and 16 have been rejected under 35 U.S.C. 102(b) as being anticipated by *Gupta et al* (Kidney International 1999, 55, 1891-1898, hereinafter “*Gupta*”). Applicants respectfully traverse. Claims 14 and 16 have been canceled without prejudice, waiver, or disclaimer and thus rejection of those claims can be withdrawn.

For a proper rejection of a claim of the pending claims under 35 U.S.C. §102, the cited reference must disclose, teach, or suggest all elements/features of the claim at issue. See, e.g., *E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 7 U.S.P.Q.2d 1129 (Fed. Cir. 1988). Claim 1 has been amended to recite the additional step of “inhibiting vascular calcification in the human with the effective amount of pyrophosphate-type compound.” The step is not taught or suggested by *Gupta*. Instead, *Gupta* employs ferric pyrophosphate in dialysate because “[h]emodialysis patients need iron to replenish ongoing losses” and “[p]yrophosphate strongly complexes iron and enhances iron transport.” *Gupta* at Background, p. 1. Nothing in *Gupta* teaches or suggests using an effective amount of a pyrophosphate-type compound to inhibit vascular calcification as recited in amended independent claim 1. Therefore, claim 1 is novel in view of *Gupta*, and the rejection of claim 1 should be withdrawn.

If independent claim 1 is allowable over the prior art of record, then its dependent claims 5 and 11-13 are allowable as a matter of law, because these dependent claims contain all features/elements/steps of claim 1. See *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988).

In addition to foregoing reason for allowability, claim 13 recites the feature of “the pyrophosphate-type compound is administered to the human in a dialysate at a concentration from about 3 μ M to about 5 μ M.” The Examiner contends that “1.6 μ M is about 3 μ M.” Applicants disagree. In claims 11 and 12, Applicants claim ranges that encompass 1.6 μ M. In claim 13, however, the claim leaves out a range that would incorporate 1.6 μ M. Thus, through the doctrine of claim differentiation, Applicants do not admit that 1.6 μ M of claim 13 is about 3 μ M.

Claim Rejections – 35 U.S.C. § 103

4. Claims 1, 5, 9, 11-14, and 16 have been rejected under 35 U.S.C. §103(a) as being unpatentable over *Lomashvili et al.* (J Am Soc Nephrol 2005, 16, 2495-2500; IDS reference, hereinafter “*Lomashvili*”) in view of *Gupta and Russell et al.* (The Journal of Clinical Investigation 1971, 50, 961-969, hereinafter “*Russell*”). Applicants respectfully traverse.

The *Lomashvili* reference has been improperly cited as prior art. *Lomashvili* states that it was received by the journal on September 25, 2003 and was not accepted for publication until March 4, 2004. *Lomashvili* at footnote, p. 1. The publication date of *Lomashvili* reference was in 2004. *Lomashvili* at header and footnote, p. 1. The instant application, however, claims priority to a provisional application filed October 28, 2003,

which pre-dates the publication of the *Lomashvili* reference. The provisional application provides support for all of the instantly-claimed subject matter. Thus, the subject matter of the claims was not described in a printed publication before the invention by Applicant, or more than one year before the earliest effective filing date of the instant application. Therefore, the *Lomashvili* reference is not properly cited as prior art against the claims of the instant application. Moreover, it should be noted that the two co-inventors of the instant application were co-authors of the *Lomashvili* reference. Thus, if the Examiner disagrees, Applicants respectfully request that the next Office Action not be made final so that Applicants may submit affidavits in order to overcome the *Lomashvili* reference.

Because the primary reference *Lomashvili* cannot be cited, the combination of references does not render claims 1, 5, 9, 11-14 obvious. Applicants request that the rejection be withdrawn.

5. Claims 1-4, 9-10, and 14-15 have been rejected under 35 U.S.C. §103(a) as being unpatentable over *Lomashvili* in view of *Gupta* and *Sommer* (a text of inorganic chemistry, Herbert Hayward, 1906, hereinafter "*Sommer*"). Applicants respectfully traverse. Because the primary reference *Lomashvili* is not properly citable as prior art as noted above, the combination of references does not render claims 1-4 and 9-10 obvious. Applicants request that the rejection be withdrawn.


CONCLUSION

In light of the foregoing amendments and for at least the reasons set forth above, Applicants respectfully submit that all objections and/or rejections have been traversed, rendered moot, and/or accommodated, and that the now pending claims are in condition for allowance. Favorable reconsideration and allowance of the present application and all pending claims are hereby courteously requested.

Any other statements in the Office Action that are not explicitly addressed herein are not intended to be admitted. In addition, any and all findings of inherency are traversed as not having been shown to be necessarily present. Further, any and all findings of well-known art and official notice, or statements interpreted similarly, should not be considered well known for at least the specific and particular reason that the Office Action does not include specific factual findings predicated on sound technical and scientific reasoning to support such conclusions.

If, in the opinion of the Examiner, a telephone conference would expedite the examination of this matter, the Examiner is invited to call the undersigned attorney at (770) 933-9500.

Respectfully submitted,



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